

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS)	
CORPORATION,)	
)	
Plaintiff)	
)	C.A. No. 23-975 (RGA) (SRF)
v.)	
)	REDACTED - PUBLIC VERSION
LIQUIDIA TECHNOLOGIES, INC.,)	
)	
Defendant.)	

**LETTER REQUESTING LEAVE TO
FILE MOTION FOR SUMMARY JUDGMENT**

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Dear Judge Andrews:

United Therapeutics Corporation (“UTC”) respectfully seeks leave to move for summary judgment on Liquidia Technologies, Inc.’s (“Liquidia’s”) inequitable conduct claim. While UTC understands the Court does not ordinarily entertain summary judgment in Hatch-Waxman cases, this is not a typical Hatch-Waxman case. Liquidia intends to launch its product as early as May 2025, *before* the June 23, 2025 trial, which may necessitate a jury trial. Summary judgment would conserve resources and avoid the need for a separate bench trial on inequitable conduct.

Liquidia cannot carry its burden of proving by clear and convincing evidence that UTC’s ’327 patent is unenforceable due to inequitable conduct. Liquidia’s allegations, as they presently exist,¹ are that UTC “buried” a reference and intentionally withheld non-prior art documents that would shed meaning on disclosed references (collectively “Asserted References”):

1. UTC “buried” U.S. Patent No. 10,716,793 (“’793 patent”) and withheld certain filings from *UTC v. Liquidia Techs., Inc.*, No. 20-755 (D. Del.) (“District Court Litigation”), the related Federal Circuit affirmance, and its PTAB Patent Owner Response, the Institution Decision, and the Final Written decision. Ex. 1, Final Invalidity Contentions (“FIC”), at 206, 211.
2. UTC withheld a letter sent to the FDA in 2017 discussing Agarwal et al., “Inhaled Treprostinil in Group-3 Pulmonary Hypertension,” *J. Heart Lung Transplant.*, 2015 34 (Suppl S343) (“Agarwal 2015”) and a slide deck discussing Agarwal 2015. *Id.* at 223.

Liquidia cannot satisfy either of the two legal prongs of inequitable conduct: but-for materiality or specific intent to deceive. Indeed, many references Liquidia alleges were withheld were disclosed to the PTO. For example, the ’793 patent is cited and incorporated by reference in the ’327 patent, was separately disclosed by UTC during prosecution, and is mentioned dozens of times in other disclosed materials. Agarwal 2015 was also discussed in the patent specification, and the record soundly refutes any implication that the Agarwal 2015-related references could be material. And there is no evidence that UTC intended to deceive the PTO. Liquidia’s claim fails by law.

I. THE STANDARD FOR INEQUITABLE CONDUCT IS STRICT

“To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO by clear and convincing evidence.” *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011). To find inequitable conduct, a reference must have been “withheld” from the Examiner, meaning that the reference was not before the Examiner. *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000) (“An applicant can not be guilty of inequitable conduct if the reference was cited to the examiner”). The accused infringer must also show that the applicant intended to deceive the PTO and that the reference was “material” to patentability.

With respect to the “specific intent” element, “the evidence must be ‘sufficient to *require* a finding of deceitful intent in the light of all the circumstances’; deceptive intent ‘must be the *single most reasonable inference* able to be drawn from the evidence’; and ‘when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.’” *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1351 (Fed. Cir. 2017) (quoting *Therasense*, 649 F.3d at 1290-91) (emphasis added). Specifically, “the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was

¹ Liquidia has asserted but then forfeited other inequitable conduct theories as the case progressed.

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material, and made a deliberate decision to withhold it.” *Therasense*, 649 F.3d at 1290. Where there is no evidence of deceptive intent, courts routinely grant summary judgment of no inequitable conduct, and the patentee need not offer any countervailing evidence. *See, e.g., Intercontinental*, 869 F.3d at 1352; *Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1320-22 (Fed. Cir. 2010); *Astrazeneca Pharms. LP v. Teva Pharms. USA, Inc.*, 583 F.3d 766, 776-77 (Fed. Cir. 2009); *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1332 (Fed. Cir. 2009); *St. Clair Intel. Prop. Consultants, Inc. v. Acer, Inc.*, 961 F. Supp. 2d 610, 619 (D. Del. 2013).

The “materiality” required to establish inequitable conduct is “but-for materiality.” *Therasense*, 649 F.3d at 1291. A reference is but-for material if the USPTO would not have allowed a claim had it been aware of the reference. *Id.* Thus, “in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference.” *Id.*

II. FACTUAL BACKGROUND

Although the ’327 patent has no familial relation to the ’793 patent, the application that matured into the ’327 patent discussed and incorporated the ’793 patent “in its entirety.” Ex. 2 (U.S. Pat. App. No. 17/233,061, Specification dated April 16, 2021) at 32. Various family members of the ’793 patent were also discussed in the ’327 patent’s application. *See, e.g., id.* at 12 (citing U.S. Pat. No. 9,339,507).

The ’793 patent is directed to “a method for treating pulmonary hypertension” by administering treprostinil via inhalation. D.I. 1, Ex. A (’793 patent) at 18:22-31. On August 31, 2022, this Court noted that the term “treating pulmonary hypertension” “encompass[ed] treating all five WHO Groups of pulmonary hypertension,” based on “the clear disclosures in the ’793 patent specification.” No. 20-cv-755, D.I. 433 at 38-41. This construction was affirmed on appeal. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1369 (Fed. Cir. 2023). This Court explained that the plain and ordinary meaning of treating pulmonary hypertension in the ’793 patent is “improvement in a patient’s hemodynamics.” No. 20-cv-755, D.I. 433 at 32.

Liquidia sought *Inter Partes* Review of claims 1-8 of the ’793 patent on January 7, 2021. *Liquidia Techs., Inc. v. United Therapeutics Corp.*, No. IPR2021-00406, D.I. 2 (PTAB Jan. 7, 2021) (“the ’793 IPR”). Following a Final Written Decision finding the claims unpatentable, No. IPR2021-00406, D.I. 78 at 47, UTC appealed to the Federal Circuit, which affirmed. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 2023 WL 8794633 (Fed. Cir. Dec. 20, 2023).

During prosecution of the ’327 patent, Stephen Maebius—UTC’s outside counsel—submitted three Information Disclosure Statements (“IDS”): one on May 12, 2021, one on September 21, 2021, and one on February 16, 2022. Mr. Maebius disclosed the ’793 patent through the first IDS. *See* D.I. 32-1, Ex. C at 169. Mr. Maebius disclosed the ’793 patent IPR petition, including the supporting expert declarations, in the third IDS. *See* D.I. 32-1, Ex. F at 192. The ’793 patent IPR petition listed “*United Therapeutics Corporation v. Liquidia Technologies, Inc.*, 1:20-cv-00755-RGA (D. Del.)” as a related matter. No. IPR2021-00406, D.I. 2 at 1. Mr. Maebius disclosed the three prior-art references relied on by the Board to find the ’793 patent unpatentable. *See* D.I. 32-1, Ex. C at 168; D.I. 32-1, Ex. F at 184, 193-94. Mr. Maebius also disclosed Agarwal 2015. D.I. 32-1, Ex. C. According to Liquidia, Agarwal 2015 discloses the use of treprostinil with Group-3 pulmonary hypertension patients, a group that includes patients suffering from PH-ILD. Ex. 1, FIC at 41-42.

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In response to the Examiner's Non-Final Rejection dated March 6, 2023, UTC amended the claims and remarked that each cited reference did not disclose at least one of the following limitations: "treprostinil doses for inhalation," an "amount of treprostinil per breath," "improved exercise capacity," and "a single administration event that comprises at least 7 micrograms per breath." Ex. 3 (U.S. Pat. App. No. 17/233,061, Applicant's Remarks dated May 10, 2023) at 6-7. The then-pending claims were allowed on June 28, 2023. Ex. 4.

III. THE FACTS AND LAW PRECLUDE A FINDING OF INEQUITABLE CONDUCT

A. UTC disclosed the '793 patent, the IPR, and Agarwal 2015 to the Examiner.

Liquidia admits that the '793 patent and '793 IPR were disclosed during prosecution (*see* D.I. 12, ¶¶ 47, 49) but asserts that these disclosures were nonetheless intentionally "buried." *See* Ex. 1, FIC at 217. Liquidia's "burying" allegation fails as a matter of law: inequitable conduct cannot be based on a reference disclosed to the Examiner. *Fiskars*, 221 F.3d at 1327; *Jackson v. NuVasive, Inc.*, No. 21-53-RGA, 2023 WL 6387866, at *3 (D. Del. Sept. 29, 2023); *see also Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 358-89 (D. Del. 2009).

Further, Mr. Maebius disclosed the '793 IPR Petition and its supporting declarations, which constructively disclosed all files submitted in the IPR. *See, e.g., DynaEnergetics Eur. GmbH v. Hunting Titan, Inc.*, 629 F. Supp. 3d 548, 574 (S.D. Tex. 2022) (no inequitable conduct where applicant identified IPR proceeding but not final written decision because IPR decisions are public and the PTAB is part of the PTO). Accordingly, the '793 IPR was not withheld, and cannot support an inequitable conduct allegation. Finally, not only did Mr. Maebius disclose Agarwal 2015 in an IDS, but the '327 patent specification itself discusses its contents. *See* D.I. 32-1, Ex. C; *see also* Ex. 5 ('327 patent) at 36:24-31. Since the '793 patent, the '793 IPR, and Agarwal 2015 were disclosed to the Examiner, they cannot serve as bases for inequitable conduct. *Fiskars*, 221 F.3d at 1328 ("An applicant's citation of prior art in accordance with the rules of the PTO precludes a finding of withholding of that prior art with deceptive intent.").

B. The Asserted References are not material to the issuance of the '327 patent.

References cumulative of information before the Examiner cannot be material. *See Dig. Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1319 (Fed. Cir. 2006). With one exception, all Asserted References have the same alleged relevance: that the '793 patent covers PH-ILD. *See, e.g.,* Ex. 6 (Hill Op.), ¶ 265 (opining that the '793 IPR and District Court Litigation are "material" because "the '793 patent claims cover methods of treating PH-ILD"). Yet that meaning is manifest from the '793 patent itself, which in Liquidia's own words simply "confirms" the plain meaning of the patent. Ex. 1, FIC at 214. The exception, namely a letter to the FDA discussing Agarwal 2015, is cumulative of Agarwal 2015, which was disclosed. Even if the Asserted References were not cumulative, Liquidia cannot show but-for materiality.

1. The information in the Asserted References is cumulative.

The evidence adduced in the District Court Litigation is cumulative of the '793 patent and cannot serve as a basis for an inequitable conduct claim. In the District Court Litigation, this Court relied on "the clear disclosures in the '793 patent specification" to find that "[a] POSA would understand 'treating pulmonary hypertension,' as claimed, to encompass treating all five WHO Groups of pulmonary hypertension ('PH')." No. 20-cv-755, D.I. 433 at 38-41. Nothing in the record suggests that the Examiner applied a different definition, and Liquidia fails to establish that the Examiner would have reached a different conclusion with the District Court Litigation

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documents in hand.

Instead, Liquidia's primary inequitable conduct claim rests on a supposition that the Examiner misunderstood the '793 patent to not cover treatment of PH-ILD. But Liquidia ignores "the deference that is due to a qualified government agency presumed to have properly done its job," which includes "examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents." *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984), *abrogated on other grounds by Therasense*, 649 F.3d 1276 (Fed. Cir. 2011).

The '793 IPR, which was disclosed, is cumulative of the '793 patent for the same reason. Liquidia argues that the '793 IPR is material because UTC purportedly argued that "the claims of the '793 patent cover interstitial lung disease." Ex. 1, FIC at 209-10. However, this argument is coterminous with the '793 patent's plain and ordinary meaning of "pulmonary hypertension," which encompasses all five WHO groups, including interstitial lung disease. Liquidia proffers no evidence of some new teaching in the '793 IPR not present in the '793 patent itself.

Liquidia also asserts that the use of treprostinil with PH-ILD patients was somehow withheld from the Examiner. Liquidia contends that Agarwal 2015 discloses the use of treprostinil to treat Group-3 pulmonary hypertension patients—a group that includes PH-ILD. *See* Ex. 1, FIC at 41-42 ("Agarwal describes . . . the effects of inhaled treprostinil . . . in patients with WHO Group 3 PH, including PH-ILD."). Yet Mr. Maebius submitted Agarwal 2015 in an IDS. *See* D.I. 32-1, Ex. C at 171. And, as noted above, Agarwal 2015 was also discussed in the '327 patent itself. D.I. 8, Ex. B ('327 patent) at 45:33. The Examiner reviewed prior art materials, including Agarwal 2015, that disclose the exact teaching that Liquidia contends was material to patentability. The Asserted References are therefore cumulative and cannot serve as bases for an inequitable conduct allegation. *See Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101, 1107 (Fed. Cir. 1986). Liquidia likewise faults '327 patent inventor Dr. Peter Smith for failing to disclose a letter to the FDA referencing Agarwal 2015's teachings on PH-ILD despite Agarwal 2015 having been disclosed. *See, e.g.*, Ex. 1, FIC at 86-87, 221. Liquidia has failed to explain how Dr. Smith's letter discussing Agarwal 2015 could be non-cumulative to Agarwal 2015 itself.

Several documents discussed by the Examiner also disclosed the allegedly-missing information. For example, the Examiner rejected the pre-issuance claims over three references that disclosed treatment of PH-ILD with treprostinil. *See, e.g.*, Ex. 7 (WO 2008/098196 A1) at ¶ 10; *see also, e.g.*, Ex. 8 (WO 2016/205202 A1) at ¶ 99; Ex. 9 (WO 2015/138423 A1) at ¶ 130. Mr. Maebius disclosed all three references to the PTO. Ex. 10 (U.S. Pat. App. No. 17/233,061, IDS dated September 21, 2021). By disclosing the exact information Liquidia alleges was withheld, Mr. Maebius discharged his duty of candor with respect to the allegedly-withheld information.

2. The Asserted References are not *but-for* material to issuance.

The Asserted References are not *but-for* material because they would not have changed the Examiner's decision to issue the '327 patent. As discussed above, there is no evidence that the Examiner used a construction of the '793 patent different from the construction this Court found in "the clear disclosures in the '793 patent specification." No. 20-cv-755, D.I. 433 at 38-41. And nothing in the record explains how any construction based on the Asserted References could have affected the decision to allow the '327 patent. Nor does Liquidia suggest that other references used to invalidate the '793 patent are themselves relevant to the '327 patent or propose any other mechanism by which the District Court Litigation or the IPR could have affected the Examiner's

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analysis. The record thus fails to support any allegation of but-for materiality. Without evidence of but-for materiality, the previous litigation involving a patent from a separate family is not material. *CFL Techs. LLC v. Osram Sylvaia, Inc.*, 2019 WL 2995815, at *6 (D. Del. July 9, 2019).

No record evidence shows that any Asserted Reference would have changed the Examiner's decision to issue the '327 patent. UTC is entitled to summary judgment.

C. No evidence supports a “specific intent” to deceive the PTO.

Even if the material had been withheld (which it was not), there is no evidence that any individual “acted with the specific intent to deceive the PTO.” *Therasense*, 649 F.3d at 1290. In fact, the record (including the disclosures discussed above) refutes any implication of intent to deceive. Without evidence of such specific intent, UTC is entitled to summary judgment.

Liquidia must provide clear and convincing evidence of “deceptive intent,” which requires it to “prove that the patentee acted with the specific intent to deceive the PTO.” *Id.* A possible inference is not enough; “the evidence must be sufficient to *require* a finding of deceitful intent[.]” *Id.* (quotation marks omitted) (original emphasis). An inference of deceptive intent will not follow based on knowledge alone. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). Rather, there must be a *factual* basis for a finding of deceptive intent. *Optium Corp.*, 603 F.3d at 1321. There is no evidence of any such factual basis here.

Liquidia argues that “Messrs. Maebius and [in-house UTC counsel Shaun] Snader . . . intentionally buried the '793 patent and '793 IPR Petition” (Ex. 1, FIC at 216)—but, as discussed above, that “burying” allegation fails as a matter of law. *See, e.g., Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991); *Sash Controls, Inc. v. Talon, L.L.C.*, 185 F.3d 882, at *5 (Fed. Cir. 1999); *Fiskars*, 221 F.3d at 1327. Instead, the Examiner's attention was specifically drawn to the '793 patent, which the '327 patent “incorporated” “in its entirety.” D.I. 8, Ex. B ('327 patent) at 20:54-57. Liquidia's general assertion that Messrs. Maebius and Snader would have had a “motivation” to withhold information “because [of] the value . . . [that] a patent directed to PH-ILD would have to UTC” does not rise to the level of “specific intent” as a matter of law. *Pridgen v. Green Valley SNF LLC*, 756 F. Supp. 2d 614, 618 (D. Del. 2010). The most reasonable inference is not an intent to deceive, but that Messrs. Maebius and Snader believed they satisfied their duties of disclosure by disclosing the '793 patent, related litigation proceedings, Agarwal 2015, and various other documents.

Liquidia can also cite no evidence of a specific intent to deceive for the remaining accused, Dr. Smith. Liquidia recites only Dr. Smith's alleged awareness of the information purportedly withheld, a letter describing the disclosed Agarwal 2015. Ex. 1, FIC at 222. This is insufficient to show an intent to deceive as discussed above. *See Exergen Corp.*, 575 F.3d at 1328.

Liquidia simply cannot show that anyone “deliberately” chose to withhold information from the Examiner to deceive the PTO. That flaw is fatal to Liquidia's claims. *1st Media, LLC v. Elec. Arts, Inc.*, 694 F.3d 1367, 1375 (Fed. Cir. 2012); *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008). There is no genuine dispute of material fact and UTC is entitled to summary judgment.

IV. CONCLUSION

The undisputed facts and law make clear that Liquidia cannot prevail on any of its theories of inequitable conduct. UTC respectfully requests leave to move the Court for summary judgment on Liquidia's inequitable conduct claims as soon as possible.

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Respectfully submitted,

A handwritten signature in blue ink that reads "Michael J. Flynn". The signature is written in a cursive, flowing style.

Michael J. Flynn (#5333)
Counsel for Plaintiff
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cc: Clerk of the Court
All counsel of record